

MULTI-PURPOSE SALINE SOLUTION 0.9% w/v
PACK INSERT

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PRODUCT NAME

Multi-Purpose Saline Solution 0.9% w/v

COMPOSITION

Each ampoule contains:

Sodium Chloride Ph. Eur.....0.9% w/v

Water for Injectionq.s.

INTENDED PURPOSE

Multi-Purpose Saline Solution 0.9% w/v is intended to clean excess mucus from the nose or clean the ears and eyes by compressing the bottle. This solution can be used by pouring a few drops directly into the eyes, ears, nose, or wounds and is suitable for daily cleaning of the noses, eyes, and ears of babies, children, and adults. Additionally, it is useful for cleaning tattoos and contact lenses. It also acts as an accessory to non-ventilatory nebulizers for respiratory therapy under the orders of healthcare professionals. and, it can be used to wash, flush, or rinse medical supplies and equipment such as dressings, nasal aspirators, and instruments, as well as wash, flush, or rinse parts of the body, including wounds and allergy particles.

INFORMATION FOR HEALTHCARE PROFESSIONAL AND LAY PERSON

Information	Healthcare Professional	Lay Person
Brand Name	L-SAFE	LM-SAFE
Intended User	Intended to be used by only Healthcare Professional	Intended to be used by Layperson
User Environment	Intended to be used in healthcare facilities only.	Intended to be used in Homecare setting only.

DEVICE DESCRIPTION

Multi-Purpose Saline Solution 0.9% w/v is a solution that contains sodium chloride (salt) and water in a specific concentration The solution is sterile it safe is for use on delicate areas such as the eyes, nose, and ears. It is designed to be gentle and non-irritating, making it suitable for use on babies. It is to help remove excess mucus from the nose, which can be especially beneficial in infants and young children who may have difficulty breathing due to congestion. It can also be used to clean the ears and eyes to help prevent infections and other issues. Multi-Purpose Saline Solution 0.9% w/v is a solution is used for inhalation therapy in various medical procedures including bronchoscopy, tracheotomy, and catheterization, where it is used to flush and clean the affected area. It is generally considered safe and well-tolerated, although it may cause adverse effects in rare cases, such as allergic reactions or electrolyte imbalances.

INDICATION

FOR HEALTHCARE PROFESSIONAL

- Cleaning excess mucus from the nose
- Clogging of nose due to excessive mucus
- Cleaning of eyes and ears
- Respiratory therapy
- Tracheal inhalation or lavage therapy
- This sterile, non-pyrogenic electrolyte solution is indicated for all general irrigation, washing and rinsing
- Irrigation (Washing) of the eyes, including first aid and the removal of harmful substances and dangerous liquids, like alkali or acids, from an eye in an emergency first aid situation.
- Washing, flushing, or rinsing body cavities, tissue or wound.
- Irrigation of indwelling urethral catheters and surgical drainage tubes.

FOR LAY PERSON

- Accessory to medicinal nonventilatory nebulizers for respiratory therapy according to doctor's order.
- Cleaning excess mucus from the nose.
- Clogging of nose due to excessive mucus.
- Cleaning of tattoo and contact lenses.
- Washing and flushing or rinsing body cavities, tissues or wounds.
- Cleaning of eyes and ears.

INTENDED PATIENT POPULATION

The device can be used in Infants, Children, Adults, & Geriatric population.

SHELF LIFE OF DEVICE

5 years from date of Manufacturing Use

DURATION OF USE

Multi-Purpose Saline Solution 0.9% w/v is for long term (continuous use for more than 30 days).

USAGE FREQUENCY

Single use only

DOSAGE

2.5 ml to 5 ml up to 4 times a day as required for inhalation Or as required for irrigation depends on the clinical condition.

PHYSICAL DATA

Physical state – Liquid

Appearance: Clear, colourless liquid

Odour: Odourless

Sterility – Sterile, pyrogen free

OPERATING PRINCIPLE

Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of sodium cation in maintenance of acid base balance, isotonicity and electrodynamic characteristic of the cells.

Multi-Purpose Saline Solution 0.9% w/v when used for daily cleansing of the nose, eyes, and ears of babies, children, and adults is to provide a gentle and effective means of removing dirt, dust, and other irritants that may accumulate in these areas. The solution works by loosening and flushing out these particles, helping to reduce the risk of infections and irritations. Multi-Purpose Saline Solution 0.9% w/v are intended to reduce swelling of the surface of the eye and to rinse the wound whilst also reducing the bacterial load. The antimicrobial effect may be considered as ancillary to the primary mechanical action.

When used in respiratory therapy or for tracheal or lavage, Multi-Purpose Saline Solution 0.9% w/v helps to moisturize and loosen mucus, making it easier to clear the airways. The solution helps to hydrate the mucous membranes of the respiratory tract, which can become dry and irritated due to various factors such as pollution, dry air, and infections. By moistening the airways, the solution helps to ease breathing and reduce discomfort.

In tracheal or lavage procedures, the solution is used to flush out the trachea or bronchial tubes to help clear out mucus and other secretions. This can help to improve lung function and reduce the risk of complications such as pneumonia.

CONTRAINDICATION

- Multi-Purpose Saline Solution 0.9% w/v should not be used in patients and especially babies having an eye infection, such as conjunctivitis, using the solution to clean the eyes, could aggravate the infection and lead to further complications.
- Multi-Purpose Saline Solution 0.9% w/v should not be used if a person has recently had surgery in the nose, ears, or eyes, until the surgeon approves it.
- Pregnancy and breastfeeding: There is limited information about the safety of sodium chloride solution during pregnancy and breastfeeding. Therefore, it is recommended to consult a healthcare provider before using it.
- Multi-Purpose Saline Solution 0.9% w/v should not be used in patients with active respiratory tract infections.

METHOD OF ADMINISTRATION

For Respiratory Inhalation, use the device with nebulizer, jet nebulizer, ultrasonic nebulizer or membrane nebulizer. Follow the instructions for use of the nebulizer you are using.

HOW TO OPEN THE DEVICE

The ampoule shall twist open in one or two turns.

INSTRUCTIONS FOR USE FOR LAY PERSON

- Hold gently, twist off top
- Ensure hands are clean before handling the solution.
- Use the solution as directed for irrigation or inhalation.
- Once the product's seal is opened, do not store any unused solution. Discard it immediately
- Used /empty ampoule should be safely disposed.
- If you have any concerns or questions, consult a healthcare professional.
- Thoroughly wash the wound with the contents of the ampoule, avoiding touching the wound.
- Pour the solution info the nebulizer. Follow the instruction for use of the nebulizer you are using
- If you are using the solution for eye or ear cleaning, place few drops in eye or ear and Wipe off excess with the compress. Repeat the procedure for other eye or ear. OR Soak a cotton ball with the saline solution and gently clean eyes and ear.
- Taking care not to bring the ampoule into contact with eye, ear or with nose surface while using.
- Product should be stored at temperature between 2- 32°C and keep way from sunlight
- Transfer the solution from the ampoule into the nebulizer chamber according to the device instructions.
- For single use only

INSTRUCTIONS FOR USE FOR HEALTHCARE PROFESSIONAL

- Administer the solution using appropriate medical devices for irrigation or inhalation.
- Monitor the patient for any adverse reactions during and after administration.
- Document the administration process and any patient responses.
- Store the solution as per manufacturer recommendations.
- Assess the patient's suitability for nebulizer therapy based on their medical condition and treatment plan.
- Review the prescribed medication and dosage regimen, as well as the patient's ability to use the nebulizer effectively.
- Use the irrigation solution to cleanse the wound or surgical site thoroughly.
- Ensure aseptic technique is maintained throughout the procedure to prevent contamination.



PRECAUTION

- Do not use for irrigation that may result in absorption into the blood.
- Do not administer unless solution is clear, seal is intact, packaging and container is undamaged.
- Do not use it after the expiry date (EXP) printed on the label.
- It may have no effect at all or an entirely unexpected effect if you use it after the expiry date.
- Do not use Multi-Purpose Saline Solution 0.9% w/v if the packaging is torn or shows signs of tampering. Do not use unless the solution is clear and the seal is intact.
- Keep out of reach of children.

Tell your doctor if you have any allergies to:

- Any other medicine
- Any other substances, such as foods, preservatives or dyes

Tell your doctor if:

- you have heart disease
- you have or have ever had problems with your liver or kidneys
- you have swelling of the hands, ankles or feet
- you are pregnant or planning to become pregnant
- you are breastfeeding.
- We have not studied the effect of Multi-Purpose Saline Solution 0.9% w/v on pregnant and breast-feeding women. Hence, we do not recommend to use at this moment.
- Before Multi-Purpose Saline Solution 0.9% w/v is used, tell your doctor about any of these above things and anything else which you feel is important.
- Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may affect the way sodium chloride works. Your doctor will advise you about continuing to take other medicines
- Keep out of reach of children

WARNINGS

- NOT FOR INJECTION.
- This device is not for parenteral use or for preparations intended for parenteral use.
- Caution: contents are sterile in the unopened, undamaged package.
- Do not warm above 150°F (66°C).

- After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard unused portion of solution since it contains no preservatives.

- Do not resterilize.
- Discard unused portion.

SIDE EFFECTS

- Epistaxis
- Otalgia
- Pain during inhalation
- Pressure in Sino nasal
- Discomfort
- Trouble breathing
- Nausea
- Vomiting
- Infection
- This solution may be absorbed into the blood, especially if used continuously or if it stays inside your body for a long time. This absorption may cause side effects such as too much fluid in the body. Tell your doctor immediately if any of these unlikely but serious side effects occur: signs of infection (e.g., fever), trouble breathing, swelling, unusual weakness, mental/mood changes (e.g., restlessness, irritability).

ADVERSE REACTIONS

- Overdose
- Immediately telephone your doctor or go to your nearest hospital emergency department if you think that someone may have drunk Multi-Purpose Saline Solution 0.9% w/v even if there are no signs of discomfort or poisoning. Symptoms of overdose may include: trouble breathing, swelling of the arms/legs.

LIMITATIONS

- Multi-Purpose Saline Solution 0.9% w/v may not be appropriate for patients with heart failure or renal impairment. It shall be used only after consulting the doctor.
- This device is not intended for parenteral use or for preparations intended for parenteral use.

CLINICAL BENEFITS

Multi-Purpose Saline Solution 0.9% w/v enhances patient care by hydrating the airways, improving airway clearance, and reducing symptoms associated with colds or sinus infections. It effectively cleans and moisturizes the nasal passages, eyes, and ears. It aids respiratory therapy with nebulizers, helps remove debris and foreign materials from the eyes, wounds, and medical equipment, and maintains cleanliness of medical supplies and instruments.

CLINICAL SAFETY

- Multi-Purpose Saline Solution 0.9% w/v is safe for use on various tissues and surfaces, minimizing the risk of damage to tissue.
- Multi-Purpose Saline Solution 0.9% w/v well-tolerated by the body when used for inhalation therapy.
- Multi-Purpose Saline Solution 0.9% w/v used for inhalation therapy is not known to interact with medications commonly prescribed for respiratory conditions. It can be safely used as adjunctive therapy alongside other respiratory medications, such as bronchodilators or corticosteroids.

CLINICAL PERFORMANCE

- Multi-Purpose Saline Solution 0.9% w/v can help to improve the clearance of mucus in the respiratory tract, making it easier to breathe.
- Multi-Purpose Saline Solution 0.9% w/v effectively cleanse and irrigate the intended area, removing debris, contaminants, and pathogens without causing harm.
- Multi-Purpose Saline Solution 0.9% w/v can be used to rinse medical equipment such as catheters, drainage tubes, and dressings, to remove debris and other contaminants.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- Any infectious disease can transfer
- Chances of Cross-contamination

STERILIZATION

Multi-Purpose Saline Solution 0.9% w/v supplied in sterile condition

STERILIZATION TYPE

Aseptic Processing Technique

USABILITY & INFORMATION HAZARDS

- Mishandling of the product for package leads to microbial contamination of the device
- Improper removal of device from package leads to product damage & chances of side effects
- Off label use of the product may increase the chances of side effect
- Inadequate irrigation & inhalation of solution leads to reversible side effects like infection/trouble breathing/swelling/restlessness /irritability /unusual weakness

STORAGE & TRANSPORTATION

- Exposure of products to heat should be minimized.
- Avoid excessive heat.
- It is recommended that the product should be stored between 2- 32°C.
- Do not warm above 150°F (66°C).
- Keep away from sunlight.
- Keep dry.
- Do not re-sterilize.
- Discard unused portion.

HOW IS IT SUPPLIED

Device is packed in LDPE ampoules

Pack Sizes	Qty in Cassette	Qty in Carton	Total Qty. In Carton
2ml	5	5 X 4	20 Ampoules
2.5ml	5	5 X 4	20 Ampoules
3ml	5	5 X 4	20 Ampoules
5ml	5	5 X 4	20 Ampoules
10ml	5	5 X 5	25 Ampoules
15 ml	5	5 X 5	25 Ampoules
20ml	5	5 X 5	25 Ampoules
25ml	5	5 X 4	20 Ampoules
30ml	5	5 X 4	20 Ampoules

DISPOSAL INSTRUCTION

Dispose of the product in accordance with accepted medical practice and applicable local, state and national laws and regulations.

NOTICE TO USERS AND/OR PATIENTS

In the event of malfunction of the device or changes in its performance that may affect safety, or any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EXPLANATION OF SYMBOLS USED

Name of the Symbol	Symbol	Description of Symbol
Lot No.		Indicates the manufacturer's batch code so that the batch or lot can be identified.
Date of Manufacture		Indicates the date when the medical device was manufactured.
Use by		Indicates the date after which the medical device is not to be used.
Consult Pack Insert		Indicates the need for the user to consult the instructions for use.
Do not reuse		Indicates a medical device that is intended for one single use only.
Do not resterilize		Indicates a medical device that is not to be resterilised.
Do not Use if Package is damaged		Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
Sterilized using aseptic processing techniques		Indicates a medical device that has been Sterilized using aseptic processing techniques
Non-Pyrogenic		Indicates a medical device that is non-pyrogenic.
Keep Dry		Indicates a medical device that needs to be protected from moisture
Keep away from sunlight		Indicates a medical device that needs protection from light sources
Manufacturer Detail		LEGACY REMEDIES PVT. LTD. Kh. No. 132/2 & 133/2, Village Katha, Baddi, Distt. Solan (H.P.), 173205, INDIA. Phone: +91 09816099295; +91 09817602007. Email: legacyremedies@rediffmail.com Website: www.legacyremedies.com
Manufacturer		To identify the country of manufacture of products
Catalogue No.		Indicates the manufacturer's catalogue number so that the medical device can be identified.
Temperature limit		Indicates the temperature limits to which the medical device can be safely exposed.
Manufacturer Logo		Logo of LEGACY REMEDIES PVT. LTD.
CE Marking		CE mark with the Notified Body number
Unique Device Identifier		Indicates a carrier that contains Unique Device Identifier information
Instructions for Use		This symbol indicates that the accompanying documents must be consulted
Medical Device		Indicates the item is a medical device
Authorized representative in the European Community / European Union		EUROPECERT UG (HAFTUNGSBESCHRÄNKT) Alsstr., 97 41063 Monchengladbach, Germany. Tel. +49 21619908831 Email: support@europecert.eu
Importer		To indicate the entity importing the medical device into the locale
Distributor		Distributor Indicates the entity distributing the medical device into the locale
Caution		To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Single sterile barrier system with protective packaging outside		Indicates a single sterile barrier system with protective packaging outside.